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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,935	09/05/2003	Stefan Gafner	TOM2809US02	7014

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EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/655,935	GAFNER ET AL.	
	Examiner	Art Unit	
	Michele Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-19* is/are pending in the application.

4a) Of the above claim(s) *8-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on March 14, 2005. Acknowledgment is made of Applicant's cancellation of Claims 5, 20 and 21.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6 and 7 are under examination.

Claim Rejections - 35 USC § 102

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated Hutchens (U).

Applicant claims an extract made by a process comprising: combining dried *Scutellaria lateriflora* L. plant material with a water solution; heating said solution to at least 70°C; and separating solid material from said solution after a predetermined period, whereby said extract has a content of flavonoids, calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside lateriflorin, baicalein, lateriflorein and wogonin of at least 18% by weight.

On page 174, Column 1, under "*DOSE*", Hutchens teaches an extract of *Scutellaria laterifolia* (also known as *Scutellaria lateriflora*): "DOSE: Tincture alone, 3-12 drops in water as indicated. As an intrusion [apparent misspelling of infusion], 1 teaspoonful of the cut or powdered herb steeped in 1 cupful of boiling water for ½ hour; take every 3-4 hours for adults; in proportion for children."

Hutchens does not expressly teach that the reference extract comprises each of the claim-designated flavonoids having the claim-designated percent amount by weight. However, the plant source material and the ingredients used in the making of the plant extracts taught by Hutchens are one and the same as instantly disclosed by Applicant. Thus, the claim-designated flavonoids having the claim-designated percent amount by weight are considered inherent to the extract of *Scutellaria laterifolia* taught by Hutchens. Please note the following:

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 1-4 and 6-7 rejected under 35 U.S.C. 102(b) as anticipated by Hutchens (X) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hutchens (X) in view of Green et al. (U), and further in view of Sheu et al. (V), Wang et al. (8, Planta Med, 2002. 66(4): 535-537. Benziodizepine binding site-Structure-activity relationships of flavonoids isolated from *Scutellaria baicalensis* root.), and Charaux et al. (W).

Applicant claims an extract made by a process comprising: combining dried

Scutellaria lateriflora L. plant material with a water solution; heating said solution to at least 70°C; and separating solid material from said solution after a predetermined period, whereby said extract has a content of flavonoids, calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside lateriflorin, baicalein, lateriflorein and wogonin of at least 18% by weight. Applicant further claims the extract of claim 1 having a content of baicalin of at least 8-9% by weight. Applicant claims a process for obtaining an extract of *Scutellaria lateriflora* L. rich in flavonoids, said process comprising: combining dried *Scutellaria lateriflora* L. plant material with a water solvent to form a solution; heating said solution to at least 70°C; and separating solid material from said solution after a predetermined period, whereby said extract has a content of flavonoids calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside I, lateriflorin, baicalein, lateriflorein and wogonin, of at least 18% by weight. Applicant further claims the process of claim 3 wherein said solution is boiling water. Applicant further claims the process of claim 3 further comprising stirring the solution for a predetermined period; and, further comprising drying said extract.

On page 174, Column 1, under "*DOSE*", Hutchens teaches an extract of *Scutellaria laterifolia* (also known as *Scutellaria lateriflora*: "DOSE: Tincture alone, 3-12 drops in water as indicated. As an intrusion [apparent misspelling of infusion], 1 teaspoonful of the cut or powdered herb steeped in 1 cupful of boiling water for ½ hour; take every 3-4 hours for adults; in proportion for children."

The claims are drawn to an extract of *Scutellaria lateriflora* L. rich in claim-designated flavonoids in an amount of at least 18% by weight and having a content of

baicalin of at least 8-9% be weight; and, a method of making thereof comprising claim-designated process steps, ingredients, process steps and experimental parameters.

The referenced composition appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition for the following reasons: Although Hutches does not expressly teach that the referenced extract has a content of flavonoids calculated as the sum of the claim-designated flavonoids in amount of at least 18% by weight, the Office deems that the extract taught by Hutchens comprises the instantly claimed ingredients in the amount claimed by Applicant, since the plant source, the boiling water solution, the process steps of extraction, and the experimental parameters for the process steps of extraction are the same or essentially the same, as instantly claimed by Applicant; and, thus, the result effect for obtaining an extract of *Scutellaria lateriflora* L. having flavonoids, calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside I, lateriflorin, baicalein, lateriflorein and wogonin of at least 18% by weight; and, an extract having a content of baicalin of at least 8-9% by weight is considered inherent to the extract and the process of making the plant extracts taught by Hutchens. The referenced process of making the composition taught by Hutchens also appears to be identical to the presently claimed process of obtaining the claim-designated plant extract and is considered to anticipate the claimed process for the following reasons: Although Hutches does not expressly teach the instantly claimed process step for separating solid material from the solution after a predetermined period and stirring the solution for a predetermined period, it is generally assumed in the art that the preparation of a plant extract includes the instantly

claimed process steps, as evidenced by Green, on page 109, under "*HOT INFUSION*"; and, the process of making the composition taught by Hutchens encompasses the same or essentially the same plant source; the boiling water solution, the process steps of extraction, and the experimental parameters for the process steps of extraction, as instantly claimed by Applicant; and, thus, the result effect for obtaining an extract of *Scutellaria lateriflora* L. having flavonoids, calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside I, lateriflorin, baicalein, lateriflorein and wogonin of at least 18% by weight; and, an extract having a content of baicalin of at least 8-9% by weight is considered inherent to the extract and the process of making the plant extracts taught by Hutchens. Consequently, the claimed composition and the process of making thereof appear to be anticipated by the reference, absent evidence to the contrary.

In the alternative, even if the claimed composition and method of making thereof are not identical to the teachings of Hutchens with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to inherently possess the same characteristics of the claimed inventions particularly in view of the similar characteristics which they have been shown to share, *e.g.*, the plant source, the boiling solution, the process steps of extraction, and the experimental parameters for the process steps of extraction are the same or essentially the same, as disclosed by Applicant. Thus, the claimed composition and the claimed process of making thereof would have been obvious to those of ordinary skill in the art within the meaning of USC 103. For instance, while Hutchens clearly teaches combining dried

plant material of *Scutellaria lateriflora* L. with boiling water to form a solution, Hutchens is silent to the instantly claimed process step for separating solid material from the solution after a predetermined period and stirring the solution for a predetermined period. However, it would have been obvious to one of ordinary skill in the art to employ the instantly claimed process steps into the making of the composition taught by Hutchens to provide the instantly claimed inventions because at the time the invention was made the claim-designated process steps were known as conventional in the preparation of a plant extract. For example, on page 109, under "*HOT INFUSION*", Green teaches a method of making a hot infusion comprising combining dried plant material with boiling water, stirring the solution, and heating the solution for a predetermined time, and separating solid material from the solution. Moreover, it would have been obvious to one of ordinary skill in the art to obtain an extract of *Scutellaria lateriflora* L. having a content of flavonoids by using the instantly claimed ingredients, solvents, process steps and experimental parameters to provide the instantly claimed inventions because at the time the invention was made it was known in the art of herbal extraction to use the instantly claimed process steps to obtain flavonoids from dried plant material of a species of *Scutellaria*, as evidenced by the teachings of Sheu, Wang and Charaux. Firstly, Sheu teaches a method for obtaining various flavonoids from the plant material of a *Scutellaria* plant, *i.e.,* baicalin (I), baicalein (II), wogonin (III) by extraction with water or water/methanol or ethanol. Sheu further teaches that the content of baicalin was dependent on the source of the plant material. For example, Sheu teaches, "The price of the crude drugs is proportional to the content of I but not

related to II and III. The content of I, the most important biologically active component of Scutellariae root, in boiling water extracts of the wine-moistened samples is higher than that in extracts of untreated crude drugs by about 30%. However, it was lower when the samples were extracted with organic solvents. When the samples were soaked in water, the I content of the crude drugs decreased markedly (about half remained after 9 h soaking) but this had no effect on that of the processed samples. The processing of *Scutellariae* can effectively prevent the decomposition of I and increases its rate of extraction boiling water." Secondly, Wang teaches a method for obtaining various flavonoids from the plant material (roots) of a *Scutellaria* plant by extracting the plant material with an organic solvent and then with boiling water three times, and concentrating the extract to dryness. In another instance, Wang teaches obtaining various flavonoids from the plant material (leaves) of a *Scutellaria* plant by extracting the plant material with water and then concentrating the extract. Wang further teaches that the water solution was chromatographed on a macroporous resin with various organic solvents, such as alcohol to determine the flavonoid content of the extract. Thirdly, Charaux teaches a method for the extraction of baicalin in leaves of Scutellaria by extracting fresh leaves with hot water and acidifying while hot. One of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to provide the instantly claimed extract employing the instantly claimed process steps for obtaining an extract of *Scutellaria lateriflora* L. rich in flavonoids because at the time the invention was made it was well known in the art that the instantly claimed source of plant material, process steps, solvents, and

experimental parameters for the extraction of flavonoids from plant material of the claim-designated plant, such as the plant material taught by Hutchens, were beneficial in the extraction of flavonoids. Thus, the instantly claimed extract and the method of making thereof would have been *prima facie* obvious and a matter of optimization to provide a result effect variable to one of ordinary skill in the art practicing the invention at the time the invention was given the references before him. Furthermore, references in conventional result-effective work conditions (*e.g.*, ingredients concentrations or order of process steps, length of process, *etc.*) do not support the patentability of claimed subject matter, unless there is clear and sufficient evidence indicating such working condition(s) is/are critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" (see, e.g., MPEP 2144.05).

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note, "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward

with evidence establishing unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-277-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1654

MCF
June 13, 2005